NOV 1 4 2003

510(k) Summary of Safety and Effectiveness

1. Manufacturer and Contact Information:

Manufacturer:	Nipro (Thailand) Corporation Limited 10/2 Moo 8, Bangnomko, Sena Ayuthaya, Thailand 13110
U. S. Distributor:	Nipro Medical Corporation 3150 NW 107 Avenue Miami, FL 33172
Contact Information:	Richard D. Bliss, Jr. Quality Systems Engineering 510 Stonemont Drive Weston, FL 33326 Telephone: (954) 385-1690 Fax: (954) 385-1256

2. Device Classification Name:
The Gastroenterology and Urology Devices Panel has classified Blood Access Device and accessories as Class II. Reference 21 CFR 876.5540.

3. Intended Use:
The Nipro® SafeTouch Safety Fistula Needle is intended for use as a blood access device for blood purification and for other treatments requiring an extracorporeal circuit or larger volumes of blood. Secondly, it is designed with an active sharp safety feature requiring physical action by the clinician to aid in the prevention of accidental needle stick injuries.

4. **Device Description and Characteristics**:
This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements for the Safe Medical Device Act (SMDA) 1990.

The Nipro® SafeTouch Safety Fistula Needle includes arterial and venous fistula adapter consisting of flexible tube and needle with an active sharps safety feature (non-implanted blood access device) as described in 21 CFR 876.5540. The Nipro® SafeTouch Safety Fistula Needle was previously described in detail as part of Premarket Notification cleared by FDA under K002813 on November 21, 2000.

The fistula needle included in this 510(k) is modified to include a change in material of the Safety AVF hub from ABS to PMMA compounds consisting of Methyl Methacrylate Polymer and Butadiene Polymer and a change in the shape of the Safety AVF stopper to enhance the activation of the safety mechanism.

The sharps injury prevention system is connected between winged needle and polyvinyl chloride tubing and consists of three parts, the Safety Hub, Safety Stopper and Safety Protector. The needle is attached to the Safety Hub and is connected to the Safety Stopper. The Safety Protector then covers the Safety Hub.

The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover latches into place. The safety feature presented in this document represents a substantially equivalent version of the current brand, which previously cleared FDA in K002813.

The Nipro® SafeTouch Safety Fistula Needle includes 2 basic types of design with clamps which remain the same; fixed wing type (stationary) and turnable wing type (rotating) which is offered in 96 configurations with options within it to include needle gauge, needle length, type of needle, and tubing length availability. A table with all the device configurations is included in Section 3 of this report.

The devices are packaged sterile and are labeled for single use only. There is no ability to clean and reuse these devices. They are restricted for sale by or on the order of a physician. The results of biocompatibility data support the equivalence of the predicate device and include sterility safety, pyrogenicity, intracutaneous reactivity, systemic injection, hemolysis, implantation testing. Please refer to Tab 9 of the Biocompatibility Section.

5. Substantial Equivalence

Nipro Medical Corporation considers the modified Nipro® SafeTouch Safety Fistula Needle to be substantially equivalent to the current Nipro SafeTouch Safety Fistula Needle with regard to intended use, materials, biocompatibility, and overall performance characteristics. The labeling is equivalent to the predicate device in intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Nipro Medical Corp.
c/o Richard D. Bliss, Jr.
Quality Systems Engineering
510 Stonemont Drive
WESTON FL 33326

Re: K032777
Trade/Device Name: Nipro® SafeTouch Safety Fistula Needles
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Product Code: 78 FIE
Regulation Number: 21 CFR §880.5200
Regulation Name: Intravascular catheter
Product Code: 80 FOZ
Regulatory Class: II
Dated: October 13, 2003
Received: October 15, 2003

Dear Mr. Bliss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: **Nipro® SafeTouch Safety Fistula Needle**

Indications for Use:

The Nipro® SafeTouch Safety Fistula Needles is intended for use as a blood access device for blood purification and for other treatments requiring extracorporeal circuit. The Nipro SafeTouch Safety Fistula Needle aids in the prevention of accidental needle stick injuries. The compatibility of available configurations is the responsibility of the physician in charge.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use _ (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032777